BAKER & MCKENZIE

CLIENT ALERT

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21st Century Cures Act Changes FDA Regulation of Smartphone Apps Designed to Monitor Health or Wellness

Summary

The passage of the 21st Century Cures Act ("Act") on December 7, 2016 by the 114th Congress affects many aspects of the regulatory program for Mobile Medical and General Wellness Apps planned by the U.S. Food and Drug Administration ("FDA"). Section 3060 of the Act amends § 520 of the Federal Food, Drug, and Cosmetic Act ("FDCA") by the addition of subsection (o). New § 520(o)(1)(B) and (C) effectively removes General Wellness Apps and many Mobile Medical Apps from the jurisdiction of the FDA. Among other things, § 520(o)(3)(A), the agency must issue a final order through notice and comment rule-making to designate a Mobile Medical App or other health-related app as a device subject to the FDCA. The app must be "reasonably likely to have an adverse health consequence."

Before this enactment, and based on the FDA's statutory construction, General Wellness and low risk Mobile Medical Apps that monitor or collect data on human conditions or disease were defined as devices subject to the FDCA ("medical devices"). To that end, in a series of recent Guidance for Industry notices, the FDA had planned a compliance program based on three sub-categories of medical devices:

- General use apps that might be used in a health setting, including providing access to medical references, were not to be medical devices under the medical device definition.
- General Wellness Apps intended to collect or monitor data designed for use in "maintaining or encouraging health" or helping to reduce risk of disease through monitoring "healthy lifestyle" parameters, even as applied to otherwise healthy persons were in many cases medical devices, although subject to enforcement discretion under the compliance program.
- Mobile Medical Apps intended to aid specific patients in managing their illness were also deemed to be medical devices in large part. Low risk Mobile Medical Apps were subject to enforcement discretion. Determination of level of risk would be made by the sponsor, potentially putting the sponsor at risk for an erroneous decision.

Under the FDA's planned compliance program, self-designated low risk Mobile Medical Apps and potentially regulated General Wellness apps were to be subject to FDA's enforcement discretion policy pursuant to which the agency would defer any potential active regulation. However, the Mobile Medical Apps guidance did strongly recommend sponsor compliance with relevant parts of the Quality System Regulation for design and development where the app was a medical device even if it were subject to enforcement discretion. Design controls for standalone software would include assessment of the performance and clinical effectiveness before launch.

Under the new legislation, General Wellness apps, among others, are excluded from the scope of the FDA jurisdiction. Further, the burden of determining risk for Mobile Medical apps has been shifted to the FDA. Until the agency issues a final order, Mobile Medical and General Wellness Apps will be exempt from regulations issued pursuant to the FDCA as non-devices.

Background

There are an increasing number of health-related software applications or programs ("apps") installed on smart phones that are intended for use by consumers or patients. These apps are designed to measure parameters of human function to maintain healthy practices or to manage illness. Data may be entered by the user, but also may be provided by a sensor intrinsic to the smartphone or part of other apps – motion, location, altitude, camera, etc. Simple sensors may be used to measure skin electrical activity to monitor pulse, the electrical activity of the heart (single lead electrocardiograms), respiratory rate, or kick frequency during pregnancy. The apps may contain use specified norms to assess maximal exercise capacity, calories expended, etc. These functions are designed to promote healthy practices but may also precipitate healthcare seeking. The apps may also monitor or communicate information to healthcare providers remotely. Customers may post reviews that suggest applicability to disease management such as recovery from traumatic brain injury by use of mental exercise apps. Apps in development include software that could review "selfies" to diagnosis disease.

Food, Drug, and Cosmetics Act

Medical devices are currently statutorily defined in part by the quoted subsection § 201(g) of the FDCA:

> (h) The term "device" . . . means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—
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> > (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals… which does not achieve its primary intended purpose through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

The device definition is expansive in that the scope of diagnostic claims extends to "other conditions . . . in man."[1]

Medical Device Regulations

While higher risk devices require FDA's premarket review before marketing is permissible, many low risk devices have been classified as exempt by regulation and are only subject to general controls including establishment registration and product listing,[2] medical device reporting,[3] labeling and providing adequate

[1] This statutory interpretation assumes that the term "or other condition" is to be construed disjunctively rather than illustratively. This is an accepted approach to statutory construction of "or." *See, McNally v. United States*, 483 U.S. 350, 358-359, 107 S.Ct. 2875, 2880-2881, 97 L.Ed.2d 292 (1987) (in interpreting an "or" in a definitional section, "[b]ecause the two phrases identifying the proscribed schemes appear in the disjunctive, it is arguable that they are to be construed independently, and that the money-or-property requirement of the latter phrase does not limit schemes to defraud to those aimed at causing deprivation of money or property; *but see, Hawaiian Airlines, Inc. v. Norris*, 114 S. Ct. 2239, 2244-45 (1994) ("the word 'or' may be used to indicate 'the synonymous, equivalent, or substitutive character' of two words or phrases").

[2] 21 C.F.R. Part 807.

[3] 21 C.F.R. Part 803.

directions for use,[4] reports of corrections and removals,[5] and good manufacturing practices under the Quality System Regulation.[6]

Current Agency Guidance on Apps

Per recent FDA guidance and consensus standards governing medical devices, standalone software is subject to verification of performance and proof of the anticipated effect before marketing.[7] A recent Guidance to Industry also sets out the FDA's policy on use of Social Media to define the intended use of a product.[8] FDA notes that sponsors are not generally responsible for content on third party social media platforms and that corrections of misstatements by third party bloggers or consumers are voluntary.[9] Nonetheless, FDA states that the agency "has determined it may benefit the public health for firms to correct misinformation about their products (including, for example, situations in which a firm is aware of misinformation that may be dangerous or harmful to the public health)."[10] The Social Media Guidance did not address whether a sponsor is responsible for consumer-posted reviews on a third party platform used by a sponsor to consummate a sales transaction.

Two other Guidance for Industry more specifically address apps.[11,12] The General Wellness guidance states that these products could be subject to either the FDA's device jurisdiction as a device or be a "product [that] is a consumer product under CPSC's authority [Consumer Product Safety Commission]."[13] This deferral of determination would have resulted in the sponsor going at risk until such time as the two agency's were to resolve jurisdiction.

The General Wellness guidance considers claims to weight management, physical fitness, stress management, mental acuity, self-esteem, sleep management, or sexual function to be general wellness claims. If so, these would have been potentially subject to FDA jurisdiction. Apps that specifically reference diseases such as obesity, anorexia, anxiety disorder or muscle atrophy would have been regulated devices such a claim contained limiting language related to reduction of risk as part of a healthy living style or help in "living well" with the condition in question. CPSC and FDA have disparate requirements for compliant marketing. FDA requires claims to be based on well understood scientific evidence, for example, peer-reviewed literature that such a reduction in risk is true.[14]

The Mobile Medical App guidance divides apps into those that may or may not be medical device apps:

[4] 21 C.F.R. Part 801.
[5] 21 C.F.R. Part 806.
[6] 21 C.F.R. Part 820. FDA also notes that most software failures under Quality Systems Regulations "are due to design flaws." Mobile Medical Apps Guidance at page 13, n.20.
[7] Software as a Medical Device (SaMD): Clinical Evaluation (International Medical Device Regulators Forum) (August 5, 2016) ("Software").
[8] Guidance for Industry: Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation about Prescription Drugs and Medical Devices (June 2014) ("Social Media")
[9] Social Media Guidance at p.4, citing 47 U.S.C. § 230 (Communications Decency Act).
[10] Social Media Guidance at p.3.
[11] Guidance for Industry: Mobile Medical Applications (February 9, 2015) ("Mobile Medical Apps Guidance);
[12] Guidance for Industry: General Wellness: Policy for Low Risk Devices (July 29, 2016) ("General Wellness")
[13] General Wellness Guidance at n.1.
[14] FDA also suggests that it will provide enforcement discretion if the app is low risk, such as music played to "soothe and relax" or monitoring exercise when made in the absence of a disease or medical condition claim. The agency's examples of low risk devices opens the question of whether these apps are nonetheless legally classified as medical devices.

> *In general, if a mobile app is intended for use in performing a medical device function (i.e. for diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease) it is a medical device, regardless of the platform on which it is run.*[15] (Emphasis added.)

Examples of general use apps that were not deemed to be medical devices include copies or e-book versions of medical reference materials or other medical training materials, whether for healthcare providers or patients, and general purpose communication apps such as email, maps, and document exchange, even though they may be used for healthcare communication or provide directions to medical facilities.[16] In contrast, examples of actual or potential medical devices included both General Wellness apps such as those described in the opening background section or, more specifically, Mobile Medical Apps that refer to an illness, disease or patient. These included organization of health information; documentation or communication of potential medical conditions to healthcare providers; enabling a healthcare provider to access lifestyle data collected by the consumer; utilize built-in camera or a connected camera for purposes of documenting or transmitting pictures to supplement or augment what would otherwise be a verbal description in a consultation between healthcare providers or between healthcare providers and patients/caregivers; coaching or monitoring patients with conditions such as cardiovascular disease, hypertension, diabetes, pre-diabetes (which would include all persons with a family history or significant obesity), obesity (which includes one-third of Americans), gum disease or other condition; promotion of strategies for monitoring or capturing or trending bodily parameters (blood pressure, heart rate, pulse, respiratory rate, glucose, weight) in patients with a relevant disease or condition; assistance for a patient in maintaining a healthy weight, getting optimal nutrition, exercising and staying fit, managing salt intake, or adhering to pre-determined medication dosing schedules by simple prompting;[17] providing periodic educational information, reminders, or motivational guidance to smokers trying to quit, patients recovering from addiction, or pregnant women.[18] These products were deemed exempt from establishment registration, product listing and premarket review.

21st Century Cures Act

Section 3060 of the 21st Century Cures Act ("Act") passed by the Senate clarifies the applicability of medical device regulation to apps. Section 520 of the FDCA (21 U.S.C. 360j) is amended by adding subsection (o) which states in relevant part:

> (o) Regulation of medical and certain decisions support software.—
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> (1) The term device, as defined in section 16 201(h), shall not include a software function that is intended—
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> (A) for administrative support of a healthcare facility, including the processing and maintenance of financial records, claims or billing information, appointment schedules, business analytics, information about patient populations, admissions, practice and inventory management, analysis of historical claims data to predict future utilization or cost-effectiveness, determination of health benefit eligibility, population health management, and laboratory workflow;

[15] Mobile Medical App Guidance at p.8.
[16] Mobile Medical App Guidance Appendix A.
[17] See, *e.g*, 21 C.F.R. § 890.5050 (Product Code NXQ) which classifies a "medication reminder" as a medical device.
[18] For an updated list of Category (2) medical devices, in addition to the cited guidance, ***see also***, http://www.fda.gov/MedicalDevices/DigitalHealth/MobileMedicalApplications/ucm368744.htm

(B) for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;

(C) to serve as electronic patient records, including patient-provided information, to the extent that such records are intended to transfer, store, convert formats, or display the equivalent of a paper medical chart, so long as—

(i) such records were created, stored, transferred, or reviewed by healthcare professionals, or by individuals working under supervision of such professionals;

(ii) such records are part of health information technology that is certified under section 3001(c)(5) of the Public Health Service Act; and

(iii) such function is not intended to interpret or analyze patient records, including medical image data, for the purpose of the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;

(D) for transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results, findings by a healthcare professional with respect to such data and results, general information about such findings, and general background information about such laboratory test or other device, unless such function is intended to interpret or analyze clinical laboratory test or other device data, results, and findings; or

(E) unless the function is intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system, for the purpose of—

(i) displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines);

(ii) supporting or providing recommendations to a healthcare professional about prevention, diagnosis, or treatment of a disease or condition; and

(iii) enabling such healthcare professional to independently review the basis for such recommendations that such software presents so that it is not the intent that such healthcare professional rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient.

(2) In the case of a product with multiple functions that contains—

(A) at least one software function that meets the criteria under paragraph (1) or that otherwise does not meet the definition of device under section 201(h); and

(B) at least one function that does not meet the criteria under paragraph (1) and that otherwise meets the definition of a device under section 201(h),the Secretary shall not regulate the software function of such product described in subparagraph (A) as a device. Notwithstanding the preceding sentence, when assessing the safety and effectiveness of the device function or functions of such product described in subparagraph (B), the Secretary may assess the impact that the software function or functions described in subparagraph (A) have on such device function or functions.

(3)(A) Notwithstanding paragraph (1), a software function described in subparagraph (C), (D) or (E) of paragraph (1) shall not be excluded from the definition of device under section 201(h) if—

(i) the Secretary makes a finding that use of such software function would be reasonably likely to have serious adverse health consequences; and

(ii) the software function has been identified in a final order issued by the Secretary under subparagraph (B).

(B) Subparagraph (A) shall apply only if the Secretary—

(i) publishes a notification and proposed order in the Federal Register;

(ii) includes in such notification the Secretary's finding, including the rationale and identification of the evidence on which such finding was based, as described in subparagraph (A)(i);

(iii) provides for a period of not less than 30 calendar days for public comment before issuing a final order or withdrawing such proposed order.

(C) In making a finding under subparagraph (A)(i) with respect to a software function, the Secretary shall consider—

(i) the likelihood and severity of patient harm if the software function were to not perform as intended;

(ii) the extent to which the software function is intended to support the clinical judgment of a healthcare professional;

(iii) whether there is a reasonable opportunity for a healthcare professional to review the basis of the information or treatment recommendation provided by the software function; and

(iv) the intended user and user environment, such as whether a healthcare professional will use a software function of a type described in subparagraph (E) of paragraph (1).

(4) Nothing in this subsection shall be construed as limiting the authority of the Secretary to

(A) exercise enforcement discretion as to any device subject to regulation under this Act;

(B) regulate software used in the manufacture and transfusion of blood and blood components to assist in the prevention of disease in humans; or

(C) regulate software as a device under this Act if such software meets the criteria under section 513(a)(1)(C).

Conclusion

These provisions of the Act will require FDA to revise or withdraw the General Wellness guidance as these products are no longer medical devices. Similarly, the Mobile Medical Apps guidance will no longer be applicable as many of these products will no be longer medical devices unless and until FDA makes an affirmative decision that the particular Mobile Medical App is in a higher risk category.

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